IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re the Application of | ) Examiner: Christopher R. Stone |
| George C. Prendergast et al. | ) Art Unit: 4173 |
| Serial No. 10/551,151 | ) File No: 3882-P03161-US |
| Filed: May 18, 2006 | ) |
| For: "Novel Methods for the Treatment of Cancer" | ) |

**DECLARATION OF GEORGE C. PRENDERGAST**

I, George C. Prendergast, hereby declare that:

1. I am a co-inventor of the invention described and claimed in the application for Letters Patent, Serial No. 10/551,151, filed on May 18, 2006 in the United States Patent and Trademark Office (hereinafter the '151 application).

2. I have read and am familiar with the contents of the Official Action dated February 4, 2008 in the '151 application. I understand the Examiner to have rejected claims 38, 39, and 41-47 for allegedly failing to comply with the enablement requirement of 35 U.S.C. §112, first paragraph. The purpose of this declaration is to provide factual evidence that the claimed compounds exhibit anti-cancer effects against multiple cancer types.

3. Attached as Exhibits A and B are graphs presenting data which demonstrates the anti-cancer activity of the administration of an IDO inhibitor with a chemotherapeutic agent against lung cancer and a colon cancer, respectively. The data presented in Exhibit A was obtained as follows. C57/bl6 mice were injected with 1 x $10^6$ LLC1 lung tumor cells subcutaneously (SC) on Day 0. On Day 7, 400 mg/kg of 1-methyl-D-tryptophan was

administered perorally (PO) twice daily (BID) Monday through Friday through the length of the experiment. On Day 9, 11, and 14, 125 mg/kg of cyclophosphamide (CTX) was injected intraperitoneally (IP). On Day 15, 18, and 22, tumor volume was measured. As shown by the data presented in Exhibit A, the administration of an IDO inhibitor with a chemotherapeutic agent effectively inhibited lung cancer growth and the effect was greater than the effect of either compound administered individually or the combined effect of the compounds administered individually.

4. The data presented in Exhibit B was obtained as follows. Balb/c mice were injected with 1 x $10^6$ CT26 colon tumor cells subcutaneously (SC) on Day 0. On Day 7, 400 mg/kg of 1-methyl-D-tryptophan was administered perorally (PO) twice daily (BID) Monday through Friday through the length of the experiment. On Day 9 and 11, 125 mg/kg of cyclophosphamide (CTX) was injected intraperitoneally (IP). On Day 15, 18, and 22, tumor volume was measured. As shown by the data presented in Exhibit B, the administration of an IDO inhibitor with a chemotherapeutic agent effectively inhibited colon cancer growth and the effect was greater than the effect of either compound administered individually or the combined effect of the compounds administered individually.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued thereon.

7/8/08
Date

George C. Prendergast